K000360

21.0 510(K) SUMMARY

Submitter: **Jeneric/Pentron, Inc.**
Address: **53 North Plains Industrial Road**
Wallingford, Connecticut 06492
Contact Tel: 203-265-7397 X619
Contact Fax: 203-265-7662
Contact Person: Annmarie Tenero
Date Summary Prepared: May 26, 2000

Rx G-Universal is substantially equivalent to Rx G, K833052, Jeneric/Pentron, Inc. However, Rx G-Universal contains a small amount of Palladium for strength and toughening, which does not affect safety.

Rx G-Universal is a high noble gold-based alloy that can be cast to cast crowns, bridges, inlays, and onlays. It can also be cast as substrate that can receive porcelain/composite overlay.
Rx G-Universal is intended to be used with copings to receive porcelain/composite application to fabricate inlays, inlays, crowns, PFM bridges, and custom posts. Also, Rx G-Universal can be used for long-span bridges.

Rx G-Universal presents no galling and scarfing problem during finishing and polishing operations. It polishes easily to a high luster. The thermal expansion of the alloy makes suitable for most of the leading conventional and low-fusing porcelains available today. Higher melting temperature of this alloy demands no alternation in porcelain-firing cycles.

SIMILARITIES: Rx G-Universal and Rx G are both high noble gold-based alloys that can be cast to cast crowns, bridges, inlays, and onlays. They can also be cast as substrate that can receive porcelain/composite overlay.

DIFFERENCES: Rx G-Universal contains a small amount of Palladium for strength and toughening which does not affect safety.

INTENDED USE: Intended to cast crowns, bridges, inlays, and onlays. It can also be cast as substrate that can receive porcelain/composite overlay.

Any dentist that prescribes to their patient porcelain/composite overlays or copings to receive porcelain/composite application to fabricate inlays, inlays, crowns, PFM bridges, and custom posts. Also, Rx G-Universal can be used on patients requiring long span bridges

Safety and effectiveness are not affected because the composition and function for Rx G-Universal are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Ms. Annmarie Tenero
Jeneric®/Pentron® Incorporated
53 North Plains Industrial Road
P.O. Box 724
Wallingford, Connecticut 06492-0724

Re: K000360
Trade Name: Rx G-Universal
Regulatory Class: II
Product Code: EJT
Dated: February 3, 2000
Received: February 4, 2000

Dear Ms. Tenero:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000360

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K000360

DEVICE NAME: **Rx G-Universal**

INDICATION FOR USE:

Rx G-Universal is a high noble gold based alloy that can be cast to cast crowns, bridges, inlays, and onlays. It can also be cast as substrate that can receive porcelain/composite overlay. Rx G-Universal is intended to be used with copings to receive porcelain/composite application to fabricate inlays, inlays, crowns, PFM bridges, and custom post. Also, Rx G-Universal can be used for long-span bridges.

Rx G-Universal presents no galling and scarfing problem during finishing and polishing operations. It polishes easily to a high luster. The thermal expansion of the alloy makes suitable for most of the leading conventional and low-fusing porcelains available today. Higher melting temperature of this alloy demands no alternation in porcelain-firing cycles.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over –The-Counter-Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)** 5.0

(Division Sign-Off) Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000360